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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|-----------------|----------------------|-------------------------|------------------|
| 09/905,732 | 07/13/2001 | Brian Paul Chadwick | 28110/36120B | 8069 |
| 4743 | 7590 10/02/2002 | | | |
| MARSHALL, GERSTEIN & BORUN | | | EXAMINER | |
| 6300 SEARS TOWER 233 SOUTH WACKER | | | DECLOUX, AMY M | |
| CHICAGO, IL 60606-6357 | | | г | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | 7 |
| | | | DATE MAILED: 10/02/2002 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/905,732

Applicant(s)

Chadwick et al.

Examiner

DeCloux, Amy

Art Unit 1644



| THE WALLING DATE OF UNIS COMMUNICATION ANNA | ars on the cover shoot with the comment |
|---|--|
| Period for Reply | ars on the cover sheet with the correspondence address — |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS S | SET TO EXPIRE MONTH(S) FROM |
| THE MALEING DATE OF THIS COMMUNICATION. | |
| Extensions of time may be available under the provisions of 37 CFR 1.136 (a). I mailing date of this communication. If the point for each condition is the point for each condition. | n no event, however, may a reply be timely filed after SIX (6) MONTHS from the |
| If the period for reply specified above is less than thirty (30) days, a reply within the lift NO period for reply is specified above, the maximum statutory period will apply. Failure to reply within the set or extended period for reply will be statute assets. | |
| Failure to reply within the set or extended period for reply will, by statute, cause to the same patent term adjustment See 37 CSB 1 704(b). | |
| p-total term dejudithent. Gee 57 CFR 1.704(b). | this continunication, even if timely filed, may reduce any |
| Status 1) Responsive to communication (a) file to | |
| 1) Responsive to communication(s) filed on | |
| 2a) ☐ This action is FINAL . 2b) ☒ This action is FINAL . | |
| 3) Since this application is in condition for allowance closed in accordance with the practice under Exp | except for formal matters, prosecution as to the merits is parte Quawas C.D. 11; 453 O.G. 213. |
| Disposition of Claims | |
| 4) ☑ Claim(s) <u>1-18</u> | is/are pending in the applica |
| 4a) Of the above, claim(s) | is/are withdrawn from considera |
| 5) | is/are allowed. |
| 6) | is/are rejected. |
| 7) 🗌 Claim(s) | is/are objected to. |
| 8) 💢 Claims <u>1-18</u> | are subject to restriction and/or election requirem |
| Application Papers | are subject to restriction and/or election requirem |
| 9) The specification is objected to by the Examiner. | |
| 10) The drawing(s) filed on is/s | are all accepted or by objected to by the Examiner |
| Applicant may not request that any objection to the draw | ving(s) be held in abevance. See 37 CEB 4 85(-) |
| 11) The proposed drawing correction filed on | is: a☐ approved b)☐disapproved by the Examiner. |
| If approved, corrected drawings are required in reply to t | this Office action |
| 12) ☐ The oath or declaration is objected to by the Examine | |
| Priority under 35 U.S.C. §§ 119 and 120 | |
| 13) Acknowledgement is made of a claim for foreign pric | ority under 35 U.S.C. § 119(a)-(d) or (f) |
| a) ☐ All b) ☐ Some* c) ☐None of: | |
| 1. \square Certified copies of the priority documents have | been received |
| 2. Certified copies of the priority documents have | been received in Application No |
| 3. U Copies of the certified copies of the priority doc | liments have been received in this Netice I of |
| *See the attached detailed Office action for a list of the | certified copies not received. |
| 14)∐ Acknowledgement is made of a claim for domestic pr | iority under 35 U.S.C. § 119(e). |
| a) ☐ The translation of the foreign language provisional | application has been received |
| 15) ☐ Acknowledgement is made of a claim for domestic pr | iority under 35 U.S.C. §§ 120 and/or 121. |
| πachment(s) | |
|) Notice of References Cited (PTO-892) | 4) Interview Summary (PTO-413) Paper No(s). |
|) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) |
| Information Disclosure Statement(s) (PTO-1449) Paper No(s). | 6) Other: |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 CFR121:

Group I, claims 1-7, drawn to an isolated polynucleotide, a vector and a host cell, classified in class 435, subclasses 320.1 and 252.3, and class 536, subclass 23.1, Group II, claims 8-9, drawn to an isolated polypeptide, classified in class 530, subclass 350 and Class 514, subclass 12.

Group III, claim 10, drawn to an antibody, classified in class 530, subclass 387.9, Group IV, claims 11-13, drawn to a method for detecting a polynucleotide, classified in class 435, subclass 6,

Group V, claim 14, drawn to a method for detecting a polypeptide, classified in Class 435, subclass 7.8,

Group VI, claims 15-16, drawn to a method for identifying a compound that binds to a polypeptide, classified in class 435, subclasses 6 and 7.8,

Group VII, claims 17-18, drawn to a method of modulating activity of a polypeptide, classified in class 424, subclass 184.1.

- 2. Inventions I and IV are related as a product and a processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the isolated polynucleotide can be used for other purposes such as the production of DNA vaccines.
- 3. Inventions III and V/VII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the antibody can be used for affinity purification.
- 4. Inventions I/II/III are different products. Invention I differs from Inventions II/III in that they comprise different chemical structures and different physical-chemical properties, since Invention I includes a nucleotide while Inventions II/III consists of a polypeptide and an antibody. Inventions II and III are not related since they are classified in different classes, are structurally unique proteins (i.e. antibody and NTPase), have different biochemical properties and biological functions. Therefore Inventions I/II/III are patentably distinct.
- 5. Inventions IV/V/VI/VII are different methods. These inventions require different

process steps and endpoints. Invention IV is drawn to a method of detecting a polynucleotide, while Invention V is drawn to a method of detecting a polypeptide, and Invention VI is drawn to a method of identifying a compound that binds to said polypeptide, and accordingly said methods of these three inventions have distinct endpoints, as does Invention VII, drawn to a method of modulating the activity of said polypeptide. Inventions IV/V/VI/VII utilize different method steps and have distinct endpoints and is therefore, patentably distinct.

- 6. Because the inventions are distinct for the reasons given above and the search required for each Group is not required for the other and because each Invention has acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.
- 7. If Group I or IV is elected, the applicant is further required under 35 U.S.C. 121 to elect one of the following groups of nucleotide sequences:
- A) encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 as recited in Claims 1a and 1b, and SEQ ID NO:1 as recited in Claim 1k,
- B) encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:4 as recited in Claims 1c and 1d, and SEQ ID NO:3 as recited in Claim 1l.
- C) encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:6 as recited in Claims 1e and 1f, and SEQ ID NO:5 as recited in Claim 1m,
- D) encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:8 as recited in Claims 1g and 1h, and SEQ ID NO:7 as recited in Claim 1n,
- E) encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:9 as recited in Claims 1i and 1j.
- 8. If Group II is elected, the applicant is further required to elect **one of the following groups of amino acid sequences**:
- A) comprising the amino acid sequence of SEQ ID NO:2 as recited in Claims 8a and 8b,
- B) comprising the amino acid sequence of SEQ ID NO:4 as recited in Claims 8c and 8d.
- C) comprising the amino acid sequence of SEQ ID NO:6 as recited in Claims 8e and 8f,
- D) comprising the amino acid sequence of SEQ ID NO:8 as recited in Claims 8g and 8h,
- E) comprising the amino acid sequence of SEQ ID NO:9 as recited in Claims 8i and 8j.
- 9. If Group II/V/VI/VII is elected, the applicant is further required to elect **one of the following groups of amino acid sequences**:
- A) comprising the amino acid sequence of SEQ ID NO:2 as recited in Claims 8a and 8b,

- B) comprising the amino acid sequence of SEQ ID NO:4 as recited in Claims 8c and 8d,
- C) comprising the amino acid sequence of SEQ ID NO:6 as recited in Claims 8e and 8f,
- D) comprising the amino acid sequence of SEQ ID NO:8 as recited in Claims 8g and 8h,
- E) comprising the amino acid sequence of SEQ ID NO:9 as recited in Claims 8i and 8j.
- 10. Applicant is required, in response to this action, to elect a specific embodiment to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected embodiment, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
- 11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional embodiments which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected embodiment. MPEP § 809.02(a).
- 12. The following claim(s) are generic: claims 1, 2 and 8.
- 13. The species are distinct each from the other for the following reasons:
- A) The recited nucleic acid sequences encode different proteins which have different biochemical characteristics, structure and functions.
- B) The recited amino acid sequences have different biochemical characteristics, structure and functions
- 14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Amy DeCloux, Ph.D. Patent Examiner 9-30-2002

Patrick J. Nolan, Ph.D. Primary Patent Examiner Group 1640